

NOV 15 2013

1K13303

510(k) SUMMARY

807.92(a)(1)

COMPANY NAME: Industrial Water Solutions, Inc.
COMPANY ADDRESS: 2692 Willowlawn Street
Roanoke, Virginia 24018
TELEPHONE NUMBER: 540/772-6341
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CONTACT PERSON: Thomas P. Stewart
SUMMARY PREPARATION DATE: July 14, 2013

807.92(a)(2)

TRADE or PROPRIETARY NAME: Sharpsology 2
COMMON NAME: Reusable Sharps Disposal Container
CLASSIFICATION: Class II – Accessory Device
CLASSIFICATION NAME: Regulation Number 880.5570
Product Code MMK

807.92(a)(3)

EQUIVALENT DEVICE #1: Sure-Way Sharps Container lid
CONTAINER LID.....MAILBOX STYLE The Sure-Way Sharps Container lid ("lid") is used on the top of the Sure-Way Sharps Container and is a Mailbox Style lid. The Sure-Way Sharps Container lid has been approved under 510(k) #K992626.
EQUIVALENT DEVICE #2: Sharps Away Vertical Drop Lid
CONTAINER LID.....CANTEEN STYLE The Sharps Away Vertical drop lid is used on top of the Sharps Away Reusable Sharps Container and is a canteen style lid. The Sharps Away Vertical Drop Lid has been approved under 510(k) # 072667
EQUIVALENT DEVICE #3 Sure-Way Reusable Sharps Container
(510(k) #K992626
CONTAINER BASE: The Sure-Way Sharps Container has been approved under 510(k) #K992626. It is described as a reusable plastic container into which used needles and other medical waste are discarded. It is a nonsterile device for nonsterile applications.

807.92(a)(4)

DESCRIPTION: Industrial Water Solutions, Inc. will market and sell the Sharpsology 2 container, wall mount and lids. Industrial Water Solutions, Inc. does not own or operate any dumping, cleaning, processing, or hauling operations for any medical waste, including sharps medical waste.
This premarket notification is for a 2 gallon container, wall mount and (2) two lids only. This is the only container to be manufactured at this time. Only one size and one model.
All wash equipment, scanning software, barcode readers and any other equipment or software is solely the responsibility of the end-user to purchase and use.

The Sharpsology 2 is a reusable plastic sharps disposal container. The container is a nonsterile device for nonsterile applications. The container is intended to be used in an appropriate wall mount unit, wall bracket or stand alone tray. It features a canteen style, vertical drop lid and a mailbox style, vertical drop lid for safe and easy disposal of sharps. Simply deposit syringes vertically into the opening of the lid, and they are deposited automatically into the container. Container is easily identified as full by looking at both the fill line on the container and biohazard label attached to container. When the canteen style lid is being used and the container is full, the supplied cap is attached to the lid by turning clockwise until it snaps into place for transport. When using the mailbox style lid and the container is full, pull the rotating portion of lid forward and snap lock the rotating portion into the two locking tabs located on the front of the lid. The Sharpsology 2 has a hole in one end of the lid and container that match, a plastic cable wire tie is inserted to lock the lid to the container for transportation. Then just replace it with a clean sanitized unit. Using proper cleaning and sterilizing equipment, cleaning facility will empty and sanitize the unit and return it to the user facility to use for the next switch out. The durable high-density polypropylene specialty impact copolymer construction of the Sharpsology 2 makes it leak resistant, puncture resistant and stable. It meets or exceeds all OSHA recommendations for sharps containers, and because it is reusable, it is more environmentally friendly and less expensive than disposable alternatives. The projected life expectancy of the device is at least (5) five years. Other sharps containers using the same material for the same purpose have remained in use over (5) five years without showing failure. The container is intended to be used in healthcare settings. The container is designed to safely contain sharps prior to removal from the generating facility, during transportation and until ultimate treatment and disposal of the sharps.

The Sharpsology 2 container is inserted into a wall mount unit available from Industrial Water Solutions, Inc. that is lockable and allows access to the opening of the lid of the Sharpsology 2 container for needle disposal. Healthcare personnel drop used sharps into the opening of the lid of the container. Sharps drop to the bottom of the container. When the container is full or up to the "Fill Line" of the container, the container is then taken out of the wall mount or bracket on the wall. The label on the container has very visible "Fill Line" imprinted on the outside. The container also has a very visible fill line, as well. A new container or one that has been sanitized for reuse is then put back into the wall mount or bracket for use. The container is then ready for transport to the cleaning facility for sanitation.

A label will be attached to the outside of the container specifying the intended use of the container. A sample of this label is attached at the end of this document. (See Attachment 1)

The Sharpsology 2 container is a reusable two gallon sharps container used for the collection of sharps at the healthcare facility. The container is housed in a wall mount or bracket attached to the wall. Healthcare personnel simply drop used sharps into the vertical drop opening on top of the lid and release. The used sharps deposited into the container and drop to the bottom of the container. The container is used until it is deemed to be full by visually inspecting to see if the sharps level is up to the "Fill Line". Once the container is deemed to be full, it is then removed from the wall mount or bracket and gotten ready for transport. A new container or a used, sanitized container is then placed in the wall mount or bracket for use. The Sharpsology 2 container has no handles, but is easily picked up by placing hands on either side of the container and lifting. The average weight of the container plus sharps inside a full container will average five and seven pounds. The used or full containers are then transported to the cleaning and sanitizing facility for sanitation, inspection, packaging, and made ready for reuse. The container is lockable. Each container has a bayonet style lid closure that horizontally slides into place and is removed mechanically for emptying and cleaning. The lid features a wire tie to further help hold the lid in place.

The scientific concept for the Sharpsology 2 container was a composite of current containers on the market and what improvements might be made. The Sharpsology 2 container is made of a Polypropylene Specialty Impact Copolymer with a superior impact and puncture resistant qualities. The container itself is very similar to many containers already on the market. The lid, as well, is very similar to current market models already in use. The device is puncture resistant. The device is leak resistant. The device is labeled in accordance with OSHA requirements and ANSI standards. A biohazard label is permanently affixed to the front and back of the container by adhesive backing. The container features (4) four raised legs for stability when used in a free standing mode. The device is capable of maintaining a stable upright position during use in a free standing mode. These four feet are located on the underside of the container at all four corners.

The container does not incorporate any features to break, bend, or shear needles. The container does not incorporate any "unwinders".

The dimensions of the container are 13.173 inches wide, 11.417 tall and 5.993 inches in depth (front to back).

The dimensions of the wall mount are 16.625 inches high, 12.25 inches wide and 6.75 inches in depth. (Front to Back)

The nominal thickness of the container is 0.122 inches. The tare weight of the container is 1.68 pounds. The volume of the container 2.25 gallons up to the fill line. The color of the container and lid is natural or red. The lids are both vertical drop lids with an opening of 2.135 inches diameter for the canteen style lid and 2.5 inches by 9.5 inches for the mailbox style lid. The dimensions of the lid are 13.029 inches long by 6.194 inches wide (front to back). The nominal thickness of the lid is .138 inches.

If the canteen style lid is being used with the container, the locking cap to be used is 2.135 inches in diameter and is made from a very durable ABS material. The measurements of the base of the predicate device and the Sharpsology 2 container are entirely the same.

The material used for the container and the canteen style lid is Polypropylene Specialty Impact Copolymer. The container and lid color is a natural or red. The material used for the mailbox style lid is a "No Break" Polyethylene. Due to the structural dynamics of the mailbox style, this material gives far more integrity to the lid and prevents breakage.

The wall mount is made of ABS material, making it very durable and impact resistant. The body of the wall mount is natural and the door is clear.

Both the container and lid are natural or red in color, which allows the healthcare personnel to easily see the amount of sharps in the container to determine how full the container is at any time. The cap for the canteen style lid is also a natural color. The container is translucent and either the natural color or red allows healthcare personnel to easily see the amount of sharps in the container at any given time. The red container is commonly used in the industry and allows virtually the same ability to see sharps level as the natural color at any time. The predicate device canteen style lid is manufactured by Solutions, Inc.. They have many containers in different sizes that come in the red color. Other manufacturers of sharps containers also have several red containers available.

Both lids have openings and design that prevents anyone from putting a hand into the container, thus preventing needle stick.

807.92(a)(5)**INTENDED USE:**

The container is intended for use in healthcare settings. The container is designed to safely contain sharps prior to removal from the generating facility, during transportation and until ultimate treatment and disposal of the sharps.

The container features a canteen style, vertical drop lid or a mailbox style, vertical drop lid. The container is housed in a wall mount or bracket attached to the wall. The wall mount is made of plastic and the bracket is made of stainless steel. The container is translucent and can be selected in a natural or red color. The lid is a natural color. The container volume is 2.25 gallons.

The dimensions of the container are 13.173 inches wide, 11.417 inches high, and 5.993 inches in depth (front to back). The lid surface dimensions for the canteen style lid are 6.197 inches wide and 13.031 inches long. The dimensions for the mailbox style lid are 6.194 inches wide and 13.029 inches long. The diameter of the lid aperture for the canteen style, vertical drop lid is 2.135 inches. The opening of the lid aperture for the mailbox, vertical drop lid is 2.5 inches by 9.5 inches.

The dimensions of the wall mount are 12.25 inches wide, 16.625 inches high and 6.25 inches in depth. (front to back) The dimensions of the bracket are 12.75 inches wide, 17.125 inches high and 7 inches in depth. (front to back). The wall mount is available from Industrial Water Solutions, Inc..

807.92(a)(6)

The Sharpsology 2 reusable container is substantially equivalent to the Sure-Way Reusable Sharps Container and is constructed of a translucent, natural colored Polypropylene Specialty Impact Copolymer.

It is injection molded and varies in thickness on average 0.002". The base of the container is similar in design and ergonomic characteristics to the Sure-Way Reusable Sharps Container. The Sharpsology 2 unit is manufactured with a thick wall (0.122" ± 0.002") and stronger Polypropylene Specialty Impact Copolymer to help confer reusable qualities. A side by side comparison finds very little significant differences in the two devices.

There are no significant functional differences between the predicate device and the Sharpsology 2 container. The predicate lid for the Sure-Way container is a mailbox style lid and has a hole in the center of the lid to vertically drop sharps after use for disposal. The Sharpsology 2 mailbox style lid also has a vertical drop for disposal of sharps after use. The second lid available is a canteen style, vertical drop lid. The predicate canteen style lid is the Sharps Away Vertical Drop Lid from Solutions, Inc.. The Sharps Away canteen style lid is a vertical drop lid which allows disposal of sharps by pulling a plug that is in the hole atop of the lid. The Sharpsology 2 canteen style lid is a vertical drop lid that has a cap that screws onto the top of the lid to close it and unscrews for safe disposal of sharps after use. Both predicate lids are injected molded. The lid and container base assembly are designed to be compatible with the mechanical dumping and washing equipment. The Sharpsology 2 container has the same intended use, principles of operation, and technological characteristics as it's predicate device. No new issues of safety or effectiveness are raised. The Sure-Way container intended use says that it is to be used for the disposal of contaminated medical sharps in healthcare facilities. The Sharpsology 2 is virtually the same. The intended use for the Sharpsology 2 is said to be intended for use in healthcare settings. Pictures of both containers and lids are attached. (See attachment no 2)

COMPARISON TABLE (lid)	Sure-Way Reusable Sharps LidMailbox Style Sharps Away Reusable Sharps Lid..... Canteen Style	Sharpsology 2 Reusable Sharps Lid Mailbox Style Canteen Style
Indications for use	Healthcare Sharps	Same
Target population	Healthcare Professionals	Same
Design	Vertical Drop	Same
Materials	Mailbox Style..... High density Polyethylene (HDPE) Canteen Style.... High density Polyethylene HDPE	Mailbox Style.... "No Break" Polyethylene Canteen Style... Polypropylene Specialty Impact Copolymer
Performance	Multiple Use	Same
Mechanical safety	Vertical Drop	Same
Where used	Healthcare facilities/labs	Same
Standards met	49 CFR/HD 22 (multi-use)	Same

The Sharpsology 2 reusable container and lid are substantially equivalent to the Sure-Way Reusable Sharps Container and lid. The Sharpsology 2 canteen style lid and the Sharps Away canteen style lid are substantially equivalent.

COMPARISON TABLE (container)	Sure-Way Reusable Sharps Container	Sharpsology 2 Reusable Sharps Container
Indications for use	Healthcare Sharps	Same
Target population	Healthcare Professionals	Same
Design	Injection mold tapered	Same
Materials	High density Polyethylene (HDPE)	Polypropylene Specialty Impact Copolymer
Performance	Multiple Use	Same
Where used	Healthcare facilities/labs	Same
Standards met	49 CFR/HD 22 (multi-use)	Same

807.92(b)(1)

Over a two-day period from August 20, 2013 to August 21, 2013, fifteen (15) red colored Sharpsology 2 containers with canteen style lids and fifteen (15) red colored Sharpsology 2 containers with mailbox style lids were subjected to a simulated life-use of 105 cycles of closing, filling, depositing waste, opening, emptying, washing and sanitizing. The red Sharpsology 2 containers were from the same lot that was tested by Anama Package and Container Testing Services, Inc. in July, 2013 (Test report dated July 24, 2013). After simulated use, there were no visible signs of failure. Containers were then performance tested and passed. The labels withstood temperatures of 180 degrees, washing with cleaners at 160 degrees, rinsing at 180 degrees and wiping without any degrading at all. (See attachment no.3)

807.92(b)(2) and (3)

The Sharpsology 2 meets and exceeds the primary design characteristics needed to comply with the OSHA Blood borne Pathogens Standard. Data for the following tests have been provided and are as follows:

Free Fall Drop	49 CFR 178.603	5 drops from 4 feet	Pass
Stacking	49 CFR 178.606	24 Hours under 80 lbs.	Pass
Vibration	49 CFR 178.608	1 hour repetitive bounce	Pass
Leak Resistance	Health devices 22	24 hours filled with water	Pass
Puncture	Health Devices 22	Needle penetration force	Pass
Freestanding Capability	Health Devices 22	Full, 1/2 Full and 5% Full	Pass

"The package, as submitted and tested, visually appears to satisfy the test criteria and is capable of preventing the loss or dispersal of the contents for conditions normal to transport" (Container Testing Laboratory, Inc.) (See Attachment 2).

The impact resistance of the Sharpsology 2 container was determined in accordance with the U.S. Department of Transportation "Drop Test" (49 CFR 178.603). A laboratory test report is attached.

Method: The packages were filled for testing to 95% capacity with disposable hypodermics with attached needles. Five (5) filled packages, closed for shipment, were immediately subjected to (5) five free fall drops each from a height of 3.9 feet (1.2 meters) onto a solid concrete floor from several and all angles.

Results: The Sharpsology 2 container met with the requirements set forth in 49 CFR 178.603 when using polypropylene wire ties for the lids. The containers did not exhibit any signs of damage from the test. No Ruptures/No leakage.

The puncture resistance of the Sharpsology 2 container were determined in accordance with proposed "Safe Disposal of Medical Waste Sharps", Health Devices 122, Nos. 8-9, August-September 1993, Pages 379-380.

Method: A sample of several sections of containers were taken, including the thinnest areas of the container. The container was subjected to the penetrations and the puncture force was recorded.

Results: All samples met the requirements of the "Safe Disposal of Medical Waste Sharps", Health Devices 122, Nos. 8-9, August-September 1993, Pages 379-380. The minimum puncture force (10.15 lbf) recorded exceeds the required minimum of 3.37 lbf.

The leak resistance was determined in accordance with proposed "Safe Disposal of Medical Waste Sharps", Health Devices 122, nos. 8-9, August-September 1993, Pages 383-384.

Method: Three (3) containers were placed on a level tabletop and filled with water to the highest point that would retain water as it was being poured to them. The water-filled units were left in the upright position undisturbed for 24 hours.

Results: All containers passed with no leakage/no liquid loss.

The vibration test was determined in accordance with 49 CFR Section 178.608.

Method: Three (3) samples filled with disposable hypodermics with needles, closed for shipment, were placed on a vibration platform and vibrated in normal shipping orientation for one (1) hour at 235 CPM. Immediately thereafter, the containers were removed and examined.

Results: All containers passed with No leakage/no rupture.

The Stacking Test was determined in accordance with 49 CFR Section 178.606.

Method: Three (3) containers were filled with disposable hypodermic with attached needles, closed as for shipment and subjected to a static compression load of 78.48 pounds, equivalent to a 10 feet high stack of identical packages, continuously for 24 hours.

Results: All containers passed with No rupture/No leakage.

The Sharpsology 2 Reusable Sharps Container was found to be very stable and capable of being left in a free standing mode. All containers remain stable without tipping in accordance with OSHA specifications 29 CFR 1910-1030.

807.93 (a)(1)

CONCLUSION: The Sharpsology 2 container met or exceeded all the above tests performed. All of the above tests are standard for the FDA requirements to meet 510(k) approval. Therefore, this container has been found to be safe and effective for use as a vessel for the handling and disposal of sharps waste (i.e. needles). The Sharpsology 2 container has been found capable of preventing the loss or dispersal of the contents of sharps waste. The Sharpsology 2 container is substantially equivalent to aforementioned predicate device and performs at least as safe and effective as the legally marketed device identified as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

November 15, 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Industrial Water Solutions, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO, MN 55313

Re: K133031

Trade/Device Name: Sharpsology 2
Regulation Number: 21 CFR 880.5570
Regulation Name: Reusable Sharps Disposal Container
Regulatory Class: II
Product Code: MMK
Dated: October 29, 2013
Received: October 31, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address:

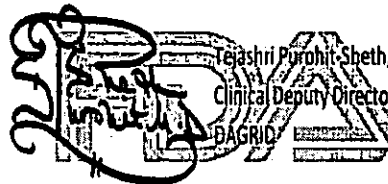
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K133031

Device Name

Sharpsology 2 Reusable Sharps Container

Indications for Use (Describe)

The container is intended for use in healthcare settings. The container is designed to safely contain sharps prior to removal from the generating facility, during transportation and until ultimate treatment and disposal of the sharps.

The container features a canteen style, vertical drop lid or a mailbox style, vertical drop lid. The container is housed in a wall mount attached to the wall. The container is translucent and can be selected in a natural or red color. The lid is a natural color. The wall mount is a natural color with a clear door. The container volume is 2.25 gallons up to the fill line.

The dimensions of the container are 13.173 inches wide, 11.417 inches high and 5.993 inches in depth (front to back). The lid surface dimensions for the canteen style lid are 6.197 inches wide and 13.031 inches long. The dimensions for the mailbox style lid are 6.194 inches wide and 13.029 inches long. The diameter of the lid aperture for the canteen style, vertical drop lid is 2.135 inches. The opening of the lid aperture for the mailbox style, vertical drop lid is 2.5 inches by 9.5 inches.

The dimensions of the wall mount are 12.25 inches wide, 16.625 inches high and 6.75 inches in depth (front to back).

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth F. Claverie -S

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